

Message Text

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PAGE 01 COPENH 02866 111657Z

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ACTION HEW-04

INFO OCT-01 EUR-12 ISO-00 SCI-04 DRC-01 RSC-01 /023 W

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R 111533Z OCT 74

FM AMEMBASSY COPENHAGEN

TO SECSTATE WASHDC 9813

INFO AMEMBASSY HELSINKI

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FOR FDA

E.O. 11652: NA

TAGS: SEL, TBIO, DA

SUBJ: ORAL CONTRACEPTIVES

1. DANISH NATIONAL HEALTH SERVICE, EFFECTIVE OCTOBER 7, 1974, HAS WITHDRAWN APPROVAL FOR PRESCRIPTION AS ORAL CONTRACEPTIVES OF A NUMBER OF MEDICAL PREPARATIONS WITH OVER 50 MICROGRAM ESTRONGEN CONTENT PER PILL. PREPARATIONS MAY STILL BE PRESCRIBED FOR OTHER THAN BIRTH CONTROL MEDICAL PURPOSES.

2. FOLLOWING PREPARATIONS ARE AFFECTED :(CONTENTS ARE INDICATED ACCORDING TO NORDIC PHARMACEUTICAL NOMENCLATURE NFN):

(A) NONOVUL (DANISH AB) WITH CONTENT OF 2.5 MILLIGRAMS LYNESTRENOLUM AND 75 MICROGRAMS MESTRONALUM IN EACH PILL;

(B) OVANON (SWEDISH ERCO) WITH CONTENT OF 7 PILLS, EACH WITH 80MICROGRAMS MESTRANOLUM, PLUS 15 PILLS, EACH WITH UT MICROGRAMS MESTRANOLUM AND 2.5 MILLIGRAMS LYNESTRENOLUM;

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(C) OVULEN (SERLE) WITH 1.0 MILLIGRAM

ETYNODIOLI ACETAS AND 100 MICROGRAMS MESTRANOLUM
IN EACH PILL;

(D) OVULEN-MITE (SERLE), SAME AS ABOVE
WITH HALF DOSE (0.5 MILLIGRAM) ETYNODIOLI ACETAS;

(E) PLAN (DANISH PHARMACIES LAB) WITH 2.0
MILLIGRAMS NORETHISTERONUM AND 100 MICROGRAM
MESTRANOLUM IN EACH PILL.

3. ACCORDING TO DANISH NHS, WITHDRAWAL OF AP-
PROVAL ON ABOVE PREPARATIONS WAS BASED ON RECOM-
MENDATION BY NHS MEDICINE CONTROL GROUP. CLI-
NICAL FOLLOW-UP REPORTS INDICATED HIGH FRE-
QUENCY OF CIRCULATORY COMPLICATIONS WITH USE
OF HIGH-ESTROGEN PREPARATIONS. NHS INFORMS
US THAT THESE AND SIMILAR PREPARATIONS WERE
TAKEN OFF APPROVED LISTS IN UK AND SWEDEN EAR-
LIER THIS YEAR AND THAT FINLAND CONTEMPLATES
SIMILAR ACTION. FINDINGS OF MEDICAL CONTROL
GROUP RESULTED FROM ROUTINE CLINICAL RESEARCH
OVER PROLONGED PERIOD OF TIME. NO CRAMATIC
OR FATAL CASES REPORTED. RESEARCH REPORT IS
EXPECTED TO APPEAR IN NEXT ISSUE OF DANISH ME-
DICAL JOURNAL. WILL TRANSMIT WHEN AVAILABLE.
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NNN

Message Attributes

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